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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/782,075	02/19/2004	Sean D. Monahan	Mirus.030.16.6	4417
25032	7590	11/29/2005		
MIRUS CORPORATION 505 SOUTH ROSA RD MADISON, WI 53719			EXAMINER CHONG, KIMBERLY	
			ART UNIT	PAPER NUMBER
			1635	
DATE MAILED: 11/29/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	10/782,075	MONAHAN ET AL.	
	Examiner	Art Unit	
	Kimberly Chong	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 19 September 2005.
- 2a) ☐ This action is FINAL.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1 and 4-14 is/are pending in the application.
- 4a) Of the above claim(s) 14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 4-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Status of Application/Amendment/Claims*

Applicant's response filed 09/19/2005 has been considered. Rejections and/or objections not reiterated from the previous office action mailed 06/28/2005 are hereby withdrawn. The following rejections and/or objections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

With entry of the amendment filed on 09/19/2005, claims 1 and 4-13 are pending in the application. Applicant has canceled claims 2 and 3.

Newly submitted claim 14 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claim 14 is drawn to a modified RNA comprising a plurality of functional groups attached to said RNA via labile bonds. The originally presented invention is drawn to a modified RNA comprising a single functional group attached via a labile bond.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 14 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

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*Priority*

The priority date granted to claims 1 and 4-13 is 02/21/2003, the filing date of the provisional application 60/448,789.

*Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The specification at page 13 defines a labile bond as a bond that can be selectively broken i.e. cleaved. The specification does not define the selective conditions that would cleave a labile bond. Therefore, for prior art purposes, any bond is labile, i.e. cleavable, under certain conditions. Thus, any modified RNA comprising a functional group post-synthetically linked to the RNA is linked via a labile bond.

Claims 1, 4-9 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Goldsborough (WO 01/94626).

Claim 1 is drawn to a modified RNA comprising a functional group post-synthetically linked to an RNA via a labile bond wherein said functional group enhances delivery of said RNA

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to a mammalian cell. Claims 4-5 limit claim 1 by reciting the modified RNA consists of a functional group is linked to a ribose 2'-hydroxyl RNA and wherein the function group is selected from a hydrophobic group, a membrane active compound, a cell penetrating compound, a targeting signal, an interaction modifier or a steric stabilizer. Claim 6 limits claim 4 by reciting the modified RNA is modified at a single ribose 2'-hydroxyl, more than one but not all of the ribose 2'-hydroxyls or all of the ribose 2'-hydroxyls. Claims 7-9 and 13 further limit claim 1 by reciting the modified RNA consists of a silylated RNA, an acylated RNA, an alkylated RNA and the modified RNA is more resistant to nucleases than an unmodified RNA.

Goldsborough disclose a modified RNA molecule comprising a function group at the 2'-hydroxyl position (see page 21) and wherein the functional groups increases the RNA molecule stability which would enhance delivery of the RNA to a mammalian cell. Goldsborough further disclose the RNA can consist of a silylated RNA (see page 25), an acylated RNA (see page 20) or an alkylated RNA (see page 21). Goldsborough disclose the modified RNA consists of a functional group attached to a ribose 2'-hydroxyl position (see page 41), the modified RNA has more than one, but not all of the ribose 2'-hydroxyl positions modified (see page 13) and the modified RNA are more resistant to nucleases (see Example 61).

Thus, Goldsborough anticipates claims 1, 4-9 and 13 of the instant application.

Claims 1, 4-5, 10 and 12-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Monia et al. (US Patent No. 6,165,789).

Claim 1 is drawn to a modified RNA comprising a functional group post-synthetically linked to an RNA via a labile bond wherein said functional group enhances delivery of said RNA to a mammalian cell. Claims 4-5 limit claim 1 by reciting the modified RNA consists of a

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functional group is linked to a ribose 2'-hydroxyl RNA and wherein the function group is selected from a hydrophobic group, a membrane active compound, a cell penetrating compound, a targeting signal, an interaction modifier or a steric stabilizer. Claim 10 limits claim 1 by reciting the composition comprises a transfection agent. Claims 12 and 13 limit claim 1 by reciting an *in vitro* or *in vivo* mammalian cell and the modified RNA is more resistant to nucleases.

Monia et al. disclose a modified RNA comprising a functional group (see column 7, lines 37-68) wherein the functional group increases the RNA molecules stability which would enhance delivery of the RNA to a mammalian cell. Bennett et al. further disclose the modified RNA can be introduced into mammalian cells using a transfection agent (see Example 9).

Thus, Monia et al. anticipates claims 1, 4-5, 10 and 12-13 of the instant application.

Claims 1, 4, 10 and 12 are rejected under 35 U.S.C. 102(e) as being anticipated by Tuschl et al. (WO 02/44321).

Claim 1 is drawn to a modified RNA comprising a functional group post-synthetically linked to an RNA via a labile bond. Claim 4 limits claim 1 by reciting the modified RNA consists of a functional group attached to the RNA and the functional group is linked to a ribose 2'-hydroxyl RNA. Claim 10 limits claim 2 by reciting the composition comprises a transfection agent and claim 12 limits claim 1 by reciting an *in vitro* or *in vivo* mammalian cell.

Tuschl et al. disclose a 2'-hydroxyl modified RNA wherein the modification comprises a functional group (see page 5 last paragraph to page 6 first paragraph). Tuschl et al. further

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disclose the modified RNA can be delivered via a transfection agent into mammalian cells *in vivo* or *in vitro* (see page 8, lines 1-18).

Thus, Tuschl et al. anticipates claims 1, 2, 4, 10 and 12 of the instant application.

Claims 1, 4 and 11 are rejected under 35 U.S.C. 102(e) as being anticipated by Tuschl et al. (US 2005/0059005).

Claim 1 is drawn to a modified RNA comprising a functional group post-synthetically linked to a RNA via a labile bond. Claim 4 limits claim 1 by reciting the modified RNA consists of a functional group attached to the RNA and the functional group is linked to a ribose 2'-hydroxyl RNA. Claim 11 limits claim 1 by reciting the RNA is a siRNA or a microRNA.

Tuschl et al. disclose a 2'-hydroxyl modified RNA wherein the modification comprises a functional group (see paragraph 0016 and 0017). Tuschl et al. further disclose the RNA consists of a microRNA or siRNA.

Thus, Tuschl et al. anticipates claims 1, 4 and 11 of the instant application.

### **Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kimberly Chong whose telephone number is 571-272-3111. The examiner can normally be reached Monday thru Friday between 7-4 pm.

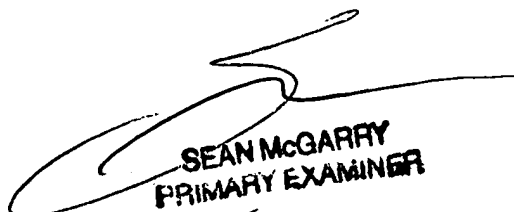
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached at 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Kimberly Chong  
Examiner  
Art Unit 1635



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PRIMARY EXAMINER  
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